Sterling

Introduction

Sterling Pharma Solutions is an FDA approved contract manufacturer and holds a current MHRA Good Manufacturing Practice (GMP) licence. The site produces bulk non-sterile material for customers and API for clinical trials, covering human health and veterinary products, and has a very successful audit history.

Sterling's quality department has over 100 staff, including operational quality and the quality control laboratories. The quality department is independent of production and has overall responsibility to ensure the appropriate level of compliance are applied to any development or manufacturing activity, as well as for the release of materials manufactured on site.

The quality department regularly performs internal audits to ensure that systems and procedures are effective and that they are being fully complied with.

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1. What regulations does Sterling comply with?

Sterling complies with current Good Manufacturing Practice (cGMP) and follows ICHQ7 guidelines.

2. What is Sterling's latest regulatory inspection history?

Oct 2019	MHRA	General 3 year inspection	GMP certificate issued
Feb 2018	FDA	General inspection	No 483's
June 2017	MHRA	General 3 year inspection	GMP certificate issued
Nov 2014	FDA	General inspection	No 483's
July 2011	PDMA	Pre-approval inspection	Approved

3. Does Sterling host customer quality audits? If yes, approximately how many per year.

Yes, Sterling holds approximately 15-20 customer audits per year in line with our customer requests.

4. How are procedures documented and controlled at Sterling?

Procedures are controlled and documented by our standard operating procedures (SOPs). These are controlled by our change control system. Documents are issued by the operational quality department. SOPs are reviewed every two years. Documents are retained in the archives for at least seven years in our limited access storage area within our warehousing facility.

5. Does Sterling utilise a vendor/supplier qualification program?

Yes, this procedure also includes the review and re-assessment of our suppliers on a regular basis. The suppliers and vendors enter into quality agreements, master service agreements (MSAs) or scope of work (SOW) with Sterling and any discrepancies or deviations are documented.

6. Does Sterling have a written procedure for customer complaints?

Yes, these procedures document the complaint, assessment and the resolution (CAPAs).

7. Does your company have written procedures to handle change management?

Full change control system operates on-site with customer approval as required by a signed quality agreement. Changes are communicated with the customer as determined by the quality agreement. Changes are approved and closed by operational quality.

8. Raw materials – does Sterling have a release and testing unit?

Yes, raw materials are tested and released by the quality and analytical teams at Sterling. Although most of the raw materials are tested, there are a few exceptions which are taken on Certificate of Analysis (COA) for safety or stability reasons. Notification of changes to the suppliers of raw materials is determined by the quality agreement. The movement and use of raw materials are controlled by our SAP system.

9. Does Sterling require customer approval for manufacturing instructions, process change controls, and process deviations?

This is determined by the signed quality agreement which outlines which notifications and pre-approval a customer requires.

10. Equipment calibration and validation – does Sterling have procedures for the calibration and validation of equipment?

Yes, Sterling has an SOP for the maintenance and calibration of the equipment across the site. Equipment cleaning and maintenance is held on our SAP system.